

**Enforceable Consent Agreement Development for
Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers**

Summary of January 29, 2004 Public Plenary Meeting

Ninety people attended the fourth public enforceable consent agreement (ECA) Plenary session on PFOA and fluorinated telomers at EPA Headquarters in Washington, DC on Wednesday January 29, 2004 from 1:00 PM to 4:00 PM. The meeting participants represented registered interested parties, observers, and EPA staff. Copies of the attendance list, the meeting agenda, and the summary presentations made by the PFOA ECA Technical Workgroups can be found in the electronic docket at OPPT-2003-0012-0378 through 0385. These presentations are reports given on behalf of the entire workgroup and not the individuals presenting the reports. The next Plenary meeting was scheduled for April 1, 2004, in Washington, DC.

I. Introduction

EPA welcomed the participants to the Plenary session and reiterated the goal of the process as obtaining agreements for development of data to identify the sources of PFOA in the environment and the pathways of human and environmental exposures.

II. Update on Developing Incineration ECAs

Richard Leukroth of EPA presented an update on behalf of the Incineration ECA Drafting Committees on progress made in development of Enforceable Consent Agreements (ECAs) for incineration testing for fluoropolymers and fluorotelomer-based polymers. The presentation included a summary of the work completed, a summary of work remaining, and a proposed schedule. The presentation is in the docket at OPPT-2003-0012-0381.

The Incineration ECA Drafting Committees reported significant progress in developing two Draft ECAs for incineration testing of fluoropolymers and fluorotelomer-based polymers. With most of the work in developing the appendices and attachments now completed, the Committees are focusing to resolve text for three remaining points to complete the ECA document (i.e., GLP/QAPP requirements, sharing CBI materials with other government organizations, and revisions to Table 1). When this work is completed, the next step will be to compile the public version Final Draft ECA document with appendices and attachments for distribution to the Interested Parties for a required 30-day comment period. As indicated in the proposed revised schedule, these comments would be compiled in time for discussion during the March Technical Workgroup meetings; and, if acceptable, the Final Draft ECAs would be presented at the Plenary on April 1, 2004 for recommendation to EPA.

Discussion/Questions: None

Conclusions:

- The Plenary group recognized the progress made by the Incineration Drafting Committees and underlined the importance of resolving the Good Laboratory Practice (GLP) and Quality Assurance Project Plan (QAPP) issues.

III. Telomer Technical Workgroup Reports

Telomer Degradation Subgroup

Speaking on behalf of the Telomer Technical Workgroup, Cathy Fehrenbacher of EPA reported on progress pertaining to telomer degradation testing agreements. The presentation included a general summary of the Technical Workgroup's discussion of draft protocols; identification of the Telomer Degradation Technical Expert Subgroup and plans for their initial meeting; summary of the Technical Workgroup's discussion of Peer and Technical consultation; and identification of the Technical Workgroup's next steps. The presentation is in the docket at OPPT-2003-0012-0382.

The Telomer Biodegradation Technical Expert Subgroup will meet on February 19 or 20, 2004. Specifics of the meeting times and locations will be determined and distributed among the Subgroup members. The Subgroup will be tasked with drafting the various technical documents necessary for the telomer degradation ECA, and will hold discussions regarding the presentation of degradation testing needs to a peer/technical consultation panel. Additional meetings will be scheduled within the Subgroup as needed.

Discussion/Questions: None

Conclusions:

- The Plenary appreciated the progress made with regard to biodegradation testing and expressed that it is essential to move quickly to close an agreement for work to begin.

Telomer Product and Article Analysis Update

Steve Korzeniowski of DuPont reported on the status of Telomer Research Program (TRP) Telomer Product and Article Analysis Letter of Intent (LOI) activities. His presentation included description of proposed testing details, summary of Technical Workgroup discussions, and path forward. The presentation is in the docket at OPPT-2003-0012-0383.

Discussion/Questions:

Bob Buck of DuPont stated that, during the Telomer Technical Workgroup meeting, EPA agreed to follow up on PFOA inhalation studies being conducted by EPA. EPA agreed that it will

obtain and distribute information on the range of PFOA-related research underway in EPA's Office of Research and Development.

EPA explained that the LOI testing information was presented to the Plenary to help the Plenary address areas of data gaps for possible ECA items.

Conclusions:

- The Plenary appreciated the progress made with regard to article testing and expressed the helpfulness of bringing this LOI information into the ECA process for discussion and feedback.

Telomer User Site Monitoring Update

Steve Korzeniowski of DuPont reported on the status of Telomer User Site Monitoring, which is also an LOI activity. He reported that TRP is continuing to work with carpet and paper industry associations to develop a program for user site monitoring. He indicated that there have been ongoing positive discussions with these associations and that TRP will continue to keep the Technical Workgroup and Plenary updated.

Discussion/Questions: None

- The Plenary expressed the importance of user site monitoring in understanding sources, pathways, and levels of exposure.

IV. Fluoropolymer Technical Workgroup Reports

Fluoropolymer Aged Article Subgroup Report

On behalf of the Fluoropolymer Technical Workgroup, George Millet of Dyneon reported on progress made with regard to the Fluoropolymer Aged Articles of Commerce ECA. His presentation included descriptions of the purpose of the study, solvent selection, test articles, equipment design, ECA development, path forward, and timeline. The presentation is in the docket at OPPT-2003-0012-0385.

The technical expert subgroup equipment design team for the Fluoropolymer Aged Articles testing ECA will schedule its first meeting in the first half of February at the EPA facility in Research Triangle Park (RTP). TRP members are also invited to come to RTP to view the EPA small chamber testing laboratory.

Discussion/Questions:

The group clarified that the Aged Articles of Commerce testing is being proposed under an ECA, while the Articles of Commerce testing is being conducted under an LOI. Although FMG reported that progress has been made on the LOI Articles of Commerce testing program, the emphasis of the presentation to the Plenary was on the ECA activity, rather than the LOI program.

Summary of Fluoropolymer Monitoring Proposals

Speaking on behalf of the Fluoropolymer Technical Workgroup, Cathy Fehrenbacher of EPA reported on the status of Fluoropolymer Monitoring. The presentation included a summary of industry's proposals on monitoring; an explanation of the phased approach; advantages and trade offs of an Memorandum of Understanding (MOU) rather than an ECA; a description of proposed Phase II sampling; an explanation of the peer consultation process; a summary of the Technical Workgroup's discussion of the proposed draft charge for peer consultation; a summary of the Technical Workgroup's discussion of peer consultation documentation and guidance; and a draft timeline for completion. The presentation also included information on Daikin's monitoring plan, which is not an MOU. The presentation is in the docket at OPPT-2003-0012-0384.

3M/Dyneon and DuPont each committed to submit by February 16, 2004, a draft MOU to EPA for distribution to and comment by the interested parties. The description of these MOUs noted that each draft MOU should detail the environmental sampling and monitoring each company proposes to undertake as their "Phase 2" MOU activity; clarify the activities they are doing in "Phase 1" (LOI activities); and specifically include and describe the peer consultation process and schedule that would determine any "Phase 3" activity recommendations. Blanks will be left in the draft MOU where specifics, for example, specific charge language regarding the peer consultation, may be inserted into a later draft of the MOU. EPA agreed to distribute the draft MOUs from 3M/Dyneon and DuPont on February 17, 2004 by email. The Fluoropolymer Monitoring Subgroup will meet on Thursday, February 26, 2004 to discuss the MOUs.

Interested parties may provide comments on Daikin's monitoring plan to Daikin or to EPA.

Discussion/Questions:

One interested party noted that the presentation on the monitoring MOUs did not reflect a consensus of what all interested parties believe would be adequate to answer the monitoring questions, but contained only the activities that the companies indicated a willingness to do.

EPA noted that the Dispersion Processors Material Balance (DPMB) study had been included on the agenda circulated in advance of the meeting, but explained that FMG had requested to defer a Plenary presentation on the study until more details were available to present.

An interested party asked about monitoring at fluoropolymer user sites. FMG indicated that releases from user sites would be addressed to some extent through the DPMB study plan. FMG noted that the DPMB analysis that has already been committed to will be conducted as designed, and next steps would be determined after that study is completed.

Conclusions:

- The Plenary group generally agreed that while an ECA was preferred, it recognized the utility of an MOU approach as the best course to proceed to get some monitoring work started. The Plenary group noted that it had hoped that all testing would be laid out in the beginning, but concluded that the tiered approach would get monitoring work underway quickly. Individual parties continued to express reservations and disappointment at the lack of an ECA on monitoring.

V. Additional Topics for Plenary Consideration

Proposed Negotiation Principles

Bob Griffin of Little Hocking Water Association presented a letter on negotiation principles which was discussed at the January 27 Telomer Technical Workgroup meeting and the January 28 Fluoropolymer Technical Workgroup meeting. He urged that all process participants affirm the negotiation principles in the letter. The letter is in the docket at OPPT-2003-0012-0305.

Discussion/Questions:

Don Duncan of Society of the Plastics Industry (SPI) clarified industry's response to the letter from Little Hocking Water Association, noting that industry felt that the detail with regard to timing in the letter was an issue, and that all of the industry participants were trying to meet the spirit of the principles discussed in the letter.

EPA responded that it is committed to open and transparent negotiations. EPA expressed concern regarding the timeframes listed in the letter. EPA agreed with the philosophy of the negotiation principles in the letter but not all of the details in the letter.

Mr Griffin recognized that the parties had raised valid concerns with respect to the timing issues contained in the letter, but noted that it was a general acceptance of the principles that he was interested in obtaining.

VI. Public Comments

A member of the public participating as a consumer product safety consultant asked what the end goal of the ECA process would be. EPA responded that the ultimate goal of the PFOA ECA process is to determine the sources of PFOA in the environment and the pathways by which

PFOA gets into human blood and the environment. EPA noted that parallel activities were underway at the Agency concerning hazard and risk assessment, and reported that the revised draft PFOA risk assessment is due to be presented to the Science Advisory Board for review in the Spring and will be available to all interested parties.

VII. Next Steps

Telomer Technical Workgroup

- EPA will obtain and distribute information on the PFOA-related studies being conducted at EPA's RTP facilities.
- EPA will obtain and distribute information on the range of PFOA-related research underway in EPA's Office of Research and Development.
- EPA will provide TRP with guidance information on mass balance studies.

Fluoropolymer Technical Workgroup

- By February 16, 2004, 3M/Dyneon and DuPont will each submit a draft Memorandum of Understanding (MOU) to EPA for distribution to and comment by the interested parties. These draft MOUs should detail the environmental sampling and monitoring each company proposes to undertake as their "Phase 2" MOU activity; clarify the activities they are doing in "Phase 1" (Letter of Intent activities); and specifically include and describe the peer consultation process and schedule that would determine any "Phase 3" activity recommendations. Blanks will be left in the draft MOU where specifics, for example, specific charge language regarding the peer consultation, may be inserted into a later draft of the MOU.
- EPA will distribute the draft MOUs from 3M/Dyneon and DuPont on February 17, 2004 by email.
- Interested parties may provide comments on Daikin's monitoring plan to Daikin or to EPA.
- EPA will provide FMG and interested parties with copies of EPA's Exposure Assessment Guidelines, EPA's Risk Characterization Policy, and the OECD Summary Exposure Reporting Format.

Upcoming Meetings

- The next meetings of the PFOA ECA Telomer and Fluoropolymer Technical Workgroups will be from 9:00 AM to 4:00 PM on Tuesday and Wednesday, March 30-31, 2004. Because meeting space at EPA was not available, these meetings will be held at the offices of the Society of the Plastics Industry, located at 1801 K Street, NW, Washington, DC. Maps and directions will be made available as the meeting dates approach. Notwithstanding the change of accustomed venue, the meetings remain open to the public.
- The next meeting of the PFOA ECA Plenary Session will be Thursday, April 1, 2004, from 1:00 to 4:00 PM in Room 1153, EPA East Building, 1201 Constitution Avenue, NW, Washington, DC.

- Additional meetings may be scheduled at EPA during Tuesday through Thursday, April 20-22, 2004, if needed.

VI. Closing Remarks

EPA thanked the members of the plenary session for their participation and attendance.